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Chemosphere 288 (2022) 132364

Contents lists available at ScienceDirect

Chemosphere

journal homepage: www.elsevier.com/locate/chemosphere

Reuse of medical face masks in domestic and community settings without sacrificing safety: Ecological and economical lessons from the Covid-19 pandemic

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HIGHLIGHTS

- 10 cycles of washing or 5 washing followed by 5 autoclaving cycles have been tested.
- Medical masks can be reused up to 10 times with a cleaning method between each use.
- Masks retain their breathability/filtration capability after 10 cycles of cleaning.
- Treated masks lack of their CE marking but are qualified with S76-001 AFNOR norm.
- Pragmatic guidance will allow to generate 10 times less plastic in the environment.

ARTICLE INFO

Handling Editor: Y Yeomin Yoon

ABSTRACT

The need for personal protective equipment increased exponentially in response to the Covid-19 pandemic. To cope with the mask shortage during springtime 2020, a French consortium was created to find ways to reuse medical and respiratory masks in healthcare departments. The consortium addressed the complex context of the

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https://doi.org/10.1016/j.chemosphere.2021.132364
Received 22 June 2021; Received in revised form 21 September 2021; Accepted 24 September 2021
Available online 29 September 2021

Keywords:
Mask
Reuse
Covid-19
Waste management
Filtration
Polypropylene

balance between cleaning medical masks in a way that maintains their safety and functionality for reuse, with the environmental advantage to manage medical disposable waste despite the current mask designation as single-use by the regulatory frameworks. We report a Workflow that provides a quantitative basis to determine the safety and efficacy of a medical mask that is decontaminated for reuse. The type IIR polypropylene medical masks can be washed up to 10 times, washed 5 times and autoclaved 5 times, or washed then sterilized with radiations or ethylene oxide, without any degradation of their filtration or breathability properties. There is loss of the anti-projection properties. The Workflow rendered the medical masks to comply to the AFNOR S76-001 standard as "type 1 non-sanitory usage masks". This qualification gives a legal status to the Workflow-treated masks and allows recommendation for the reuse of washed medical masks by the general population, with the significant public health advantage of providing better protection than cloth-tissue masks. Additionally, such a legal status provides a basis to perform a clinical trial to test the masks in real conditions, with full compliance with EN 14683 norm, for collective reuse. The rational reuse of medical mask and their end-of-life management is critical, particularly in pandemic periods when decisive turns can be taken. The reuse of masks in the general population, in industries, or in hospitals (but not for surgery) has significant advantages for the management of waste without degrading the safety of individuals wearing reused masks.

1. Introduction

The healthcare sector has a high utilisation of single-use disposables and thus generates a large amount of waste, albeit that 20–25% of which is recyclable plastic material (Campion, et al., 2015; Byeong Kyu, 2002; Kane, 2018). Medical masks are medical-use disposables and have become essential for usage by the general community due to the need to control the Covid-19 pandemic. Governments around the world quickly mandated that wearing a mask was compulsory in public spaces. This rapidly increased the demand for respiratory and surgical masks, leading to mask shortages that forced authorities to change their policies and restrict initially the use of surgical masks to healthcare workers (HCW). At the beginning of the pandemic, one or two mask per day per person were distributed instead of following the normal practice of changing the mask for each person between each medical procedure. The consequences for that pattern of usage led to a reduced breathability in the masks and the possibility for germs to translocate. Indeed, sub-optimal recycling procedures consisted of disinfection without any cleaning step (Liao et al., 2020; Ibáñez-Cervantes et al., 2020; Cai and Floyd, 2020; Cheng et al., 2020; Bernard et al., 2020).

Concurrent with the enhanced needs for HCW, the general community was mandated to have face coverings to combat the spread of Covid-19. Since the use of medical masks was reserved initially for HCW, cloth-tissue mask face coverings were developed as a last-resort interim solution for the general community. However, their level of protection is at least 5 times less than medical masks, simply due to the structure and material used for manufacturing and the light-touch regulatory environment (SI-0).

The Covid-19 pandemic is caused by the community transmission of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) virus. The 60–140 nm virus (Zhu et al., 2020) travels in micron-size water droplets (Tang et al., 2021; Wei et al., 2021) and can also be infectious in the form of aerosols. However, the larger amount of virus is found in large particles (Wei et al., 2021).

The Type IIR medical masks are disposable medical devices following standards: NF EN 14683:2019 in Europe, ASTM F2100-19 level 1,2,3 in USA, and YY/T 0969–2013 and YY 0469–2011 in China (SI-0). Type IIR medical masks are made from at least 3 layers of non-woven polypropylene, with 2 layers (inward-facing and outward-facing) spun bond (S) polypropylene, between which a melt blown (M) higher filtration layer of polypropylene is disposed. Those 3 "SMS" layers provide an efficient network for filtration. They are certified to prevent the projection of secretions from the airways of the wearer as they filter more than 98% of 3 μm droplets from inside to outside. They are certified to protect others from the wearer's respiratory emissions. Nevertheless, they are used to protect the wearer from the respiratory emissions of others.

Despite the health-care value of Type IIR masks, such disposable masks create an environmental hazard since the complete biodegradation of polypropylene is a very slow process that requires hundreds of years (Fotopoulou and Karapanagioti, 2017, Dharmaraj et al., 2021). Moreover, the term "disposable", or indeed descriptions such as "paper masks", reinforces the accumulation of these masks as litter in the environment. Such inappropriate community disposal of contaminated masks raises health questions, not the least of which is the high cost due to environmental damage. Indeed, if good-practices for waste management or recycling have not been established then the disposal of the increased number of polypropylene masks becomes a major, and increasing, environmental pollutant. Recent publications on the subject reveal an overload of the plastic waste used during the pandemic, as occurred in Wuhan's hospital, producing 200 tonnes of medical waste in one day, which has to be incinerated by mobile treatment facilities (Saadat et al., 2020, Silva et al., 2020; Singh et al., 2020; Ardusso et al., 2021). The number of medical masks is roughly estimated between 1 and 1.3 billion per month in Italy and UK, corresponding to 66 000 tonnes/year of waste (Allison et al., 2020; Prata et al., 2020). Furthermore, during the first pandemic episode in Europe, the price of medical masks was multiplied by at least a factor 10, including the price increase of the raw material and the transport cost.

Here we take a systematic and experimental approach to the question of whether Type IIR masks can be reused. There is a complex context for this question that includes the balance between cleaning medical masks in a way that maintains their safety and functionality for reuse, with the environmental advantage to manage medical disposable waste despite the current mask designation as single-use by the regulatory frameworks. Our approach is to design a Workflow for cleaning masks that is based on elements from existing Standards to ensure the safety and function of reused medical masks. Our Workflow provides data upon which to base a possible revision of the regulatory framework for Type IIR masks. Such an evidence-based Workflow, designed to maintain the efficacy of medical masks, then provides a rational basis to respond to the needs for community protection and prevention in the face of the emergence of highly transmissible SARS-CoV-2 mutants or indeed the next virus pandemic. It also provides the basis for a possible revision of the regulations for the reuse of medical masks to address the significant broader issue of improving the sustainability of medical disposables.

2. Materials and methods

We designed a 8-stage Workflow to assure the safety and functionality of medical masks for reuse derived from existing Standards publications. The Workflow was applied to both unused (new) masks taken directly from the original packaging, and used masks collected from hospitals in Grenoble and Nancy. We anticipated the outcomes from this Workflow can provide quantifiable ways to determine and trace the reusability of medical masks.

2.1. Unused (new) masks

All the new masks used in this study are type II medical face masks following the European standard "*EN 14683+AC august 2019 Medical face masks - Requirements and test methods*", corresponding to ASTM F2100-19 (USA) and YY/T 0969–2013 (China). The properties of type IIR masks as defined by *EN 14683+AC august 2019* are as follows:

(i) the microbial cleanliness should be less than 30 CFU/g of mask.
(ii) the label "II" refers to class II masks featuring a 98% bacterial filtration efficiency (BFE) with 3 ± 0.3 μm mean particle size. This FE is measured in the direction of its normal usage, i.e. from the wearer to the environment,
(iii) the breathability refers to the differential pressure and should be lower than 40 Pa/cm^2,
(iv) the label "R" refers to a splash resistance layer protection (≥16 kPa) against body fluid spills.

The new unused 3 ply IIR-type masks (ref. CA 1960) were provided by CA diffusion to Grenoble and Nancy hospitals for all the 7 stages of the workflow (Fig. 1). The masks comprise non-woven fabric SMS (Spunbond, Meltblown, Spunbond). They contain a low amount of phenolic antioxidant (butylated hydroxytoluene, Irganox 1076). The mask fits snugly with the help of a nasal bar (pliable nose piece) and with ear loop elastic bands (containing elastane + polypropylene) or with 2 flat polypropylene ties.

In addition, ten different unused brands of masks have been tested in Nancy Hospital as a control for the washing cycles: CA diffusion 1931 (II), 2015-30 Medicom (IIR), MPB-CH1 Paul Boyé (IIR), PLM.01R Aerokyn (IIR), Earloop LyncMed 302089 (II), Sunrise Nursing (not known), TD Professional 45455 (II), The Lite One Kimberly Clark (IIR), LiangYa DGTMYY (I), Saudel 85002 (II).

2.2. Used masks

A protocol was established in different departments of Grenoble Alpes University Hospital (CHUGA) for collection of masks between 03/17/2020 and April 06, 2020, and for collection in different departments of Nancy University Hospital between 04/24/2020 and June 08, 2020.

The protocol required that containers and bags dedicated to collection were placed in the different departments where HCW left their used masks at the end of their working day. The used masks were collected within specifically labelled double packaging, transported and stored in an appropriate place. Particular attention was paid to the protection conditions of the collection personnel (wearing of gowns, masks and strict hand hygiene). A wide range of brands was used in the hospital during this period and up to 9 different references of type IIR medical masks have been collected and tested, comprising the trademarks CA diffusion, Kolmi, Valmy, Euronda, Medicom, LCH Medical product, LyncMed and Paul Boyé. Masks with ties have been excluded.

2.3. Workflow Stage 1: sorting and washing of the used masks

After collection, the reusable masks have been rapidly selected under a laminar flow cabinet. When the guidelines were properly applied, this step was no more necessary and the masks were then transferred directly to the Hospital's laundry and washed according to the recommendations of the cleaning product manufacturer. The washing step followed the existing classical closed-circuit of the hospital. The 2 procedures are summarized in the washing step procedure in SI-1 section and consist in a 60 °C washing with detergents and disinfectants solutions.

2.4. Workflow Stage 2: sterilization

(a) by autoclave

The Sterility Assurance Level (SAL) of 10^{-6} is the probability of 1-in-1-million to find a remaining living bacteria. It is frequently used for the last step of sterilization of implantable devices. Steam sterilization is the reference method for sterilizing items at the hospital and in all biology science departments. It follows the European regulation ISO 17665–1.

Before autoclaving, the masks were unfolded, bundled in lots of 10 masks, and packed in peelable see-through pouches with steam and EtO indicators BOP®. After sealing, the pouches were placed in the autoclave Advantage class B or for a treatment at 121 °C during 20min. The pouches were dried at 70 °C during 20min after this treatment to remove the condensed water inside the pouches.

(b) by cold sterilizations

Three types of cold sterilizations were conducted. The first two were beta and gamma irradiations from 20 kGy to 40 kGy. The third one was

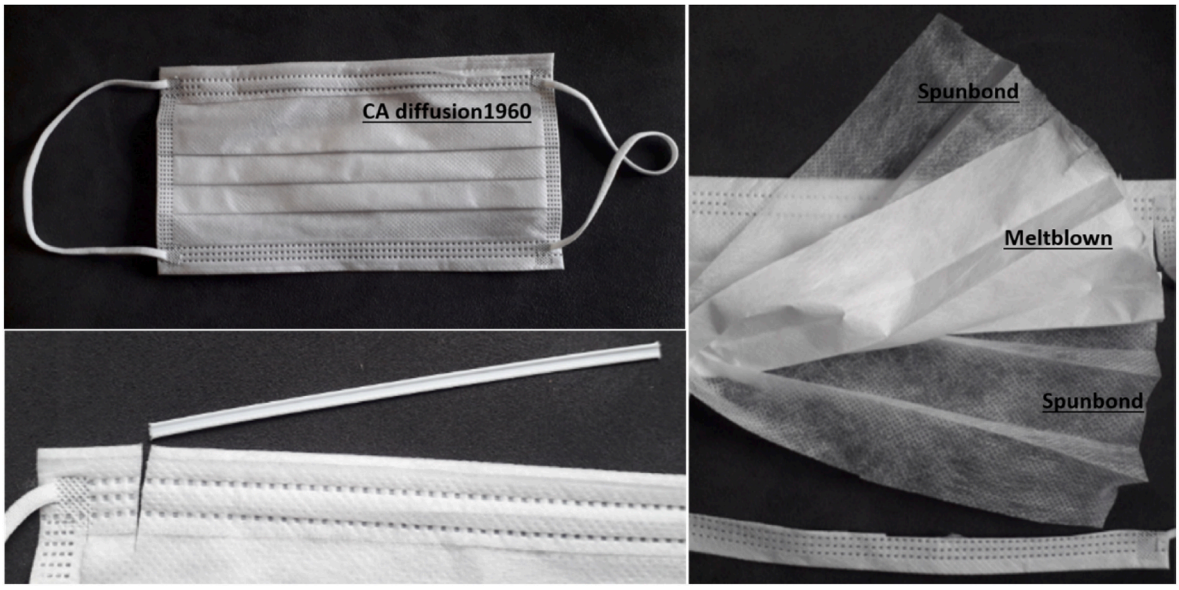

Fig. 1. Description of the type IIR new mask used in this study: a) Outside face of the mask b) Nasal bar out of the mask and its non-covered metallic extremity c) The 3 layers of a polypropylene mask.

an EO treatment consisting in an exposition of the masks to 850 mg/L EO gas during 12 h at 40 °C and 65% relative humidity (SI-2a and -2b).

2.5. Workflow Stage 3: analysis of microbial cleanliness

The microbial cleanliness was verified according appendix D of *EN 14683+AC august 2019* and described in SI-3a. Briefly, 5 washed masks per batch were tested. Each mask was weighed, incubated in a 300 mL volume extraction buffer (0,1% peptone, 0,2% Tween 20, 0,5% NaCl) for 5min at 25 °C with stirring at 250 rpm. Then a volume of 100 mL of the extraction buffer was filtered on a 0.45 μm filter fitted into a filtration apparatus. Rinsing of the filtration apparatus was performed with an additional 5 mL of sterile extraction buffer. Then, the 0.45 μm filter was removed and placed on trypticase soja agar plate. Bacterial colony counting was performed after 3 days of incubation at 30 °C. The operation was repeated with another 100 mL of the extraction buffer for yeast and fungus counting. The new filter from this second filtration was placed on Sabouraud + chloramphenicol (BD France) plates that were incubated for 7 days at room temperature before counting.

2.6. Workflow Stage 4: sporicidal claim check after washing and autoclave treatment

10^6 *Geobacillus stearothermophilus* spores were inoculated on masks under dirty soiling conditions (SI-4a) according to norms NF T72-230/231, NF EN 14347 and NF EN 13704. The spot of inoculation was marked using a permanent marker. The masks were left on the bench for 24h00 and then washed according to the Workflow Stage 1 protocol, and autoclaved (212°C-20min) using the Workflow Stage 2 protocol. Colony counting was carried out after treatment (washing or washing/autoclaving) versus untreated samples. The marked spot was cut out (3–4 cm^2) then transferred to a 15 mL tube containing 5 mL of 2 M NaCl. The tubes were placed under vigorous stirring (250 rpm) for 5min at 25 °C before being filtered through a 0.45 μm filter placed on a filtration apparatus. Rinsing of the device was performed with an additional 5 mL of sterile water. The membrane was then transferred to a trypticase soja plate and incubated at 65 °C for 24 h before colony counting.

2.7. Workflow Stage 5: particle filtration efficiency (PFE)

BFE is the existing standard method to evaluate the resistance of a face mask to the penetration of a bioaerosol of *Staphylococcus aureus*. However, we have chosen to confirm and supplement the BFE measurements with spectral PFE measurements for an inert di-ethyl-hexyl-sebacate (DEHS) liquid aerosol. The BFE and PFE techniques are comparable since the respective particle sizes are around 3 μm and their capture by a filter is the result of physical mechanisms that depend mainly in inertial impact (Brosseau et al., 1994, Wake et al., 1997; González et al., 2016). The main difference is that BFE test was expressed from the number of 1 μm viable bacteria contained in 3 μm droplets passing through the medical face mask, whereas the PFE test was calculated from the fractional number concentration of 3 μm vectors measured upstream and downstream of the mask. However, the PFE provides a more robust quantification of the spectral efficiency of the filter in capturing the inert DEHS particles since it based on optical or aerodynamic particle sizer techniques to count particles both upstream and downstream of the filter. The PFE measurements provide more reliable quantification of spectral efficiency of the filtering capability of the masks compared with microbial particle counting using culture-based methods (BFE).

(a) according to NF EN 14683

The assessment of BFE was performed according to the EN 14683:2019 standard for the performance of medical masks and using a published procedure (Pourchez et al., 2021). Test specimens with a minimum size of 100 mm by 100 mm were cut from complete masks so that the test specimen included all layers of the mask. The test specimen of the mask material was clamped between a six-stage viable Andersen cascade impactor and an aerosol chamber (glass, 445 mm long and 60 mm in external diameter). Each test specimen was conditioned in air at 21 ± 5 °C and 85 ± 5% relative humidity for a period of at least 4 h to allow equilibration with that atmosphere prior to testing. An aerosol of 3.0 ± 0.3 μm droplets was formed from a suspension of 3 mL at 2,000 CFU/mL of *S. aureus* (ATCC 6538) using an E-Flow® mesh nebulizer (Pari GmbH, Starnberg, Germany) to maintain a bacterial challenge 2200 ± 500 CFU per test with a 1min nebulization. The aerosol of *S. aureus* was introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The testing was performed with the inside of the medical face mask in contact with the airborne bacterial challenge. The FE of the mask is given by the number of colony forming units (CFU) passing through the medical face mask material expressed as a percentage of the number of CFU present in the challenge aerosol. The positive control reference was obtained by omitting the test specimen from the measurement chamber. Then, the BFE score for the mask, as a percentage, was calculated using the following formula: BFE=(C−T)/C × 100, where C is the mean of the total plate counts for the two positive control runs, and T is the total plate count for the test specimen. The testing procedure was repeated for at least 5 specimens of the mask.

(b) Inert particle filtration using PFE

The spectral PFE of the tested masks was evaluated using separate devices from two different French laboratories, the GEPEA Lab in Nantes (Génie des Procédés Environnement – Agroalimentaire, UMR 6144) and the LRGP Lab in Nancy (Laboratoire Réactions et Génie des Procédés, UMR 7274). Depending on the device that was utilised, the sample of medical face mask was placed in a filter holder with a filtration surface area of either 168 cm^2 (GEPEA Lab) or 28.3 cm^2 (LRGP Lab). A polydisperse DEHS aerosol was produced with a MAG300 Palas® generator diluted with filtered air for the device with the surface are of section 168cm^2, and with an AGK 2000Palas® generator diluted with compressed air for the device of section 28.3cm^2. The polydispersed liquid aerosol of DEHS generated in both experimental devices produced droplets between 1 μm and 3 μm to provide a comparison with the 3.0 μm droplets generated by the aerosol chamber of the BFE tests. Filtration velocity was adjusted at 9.6 cm/s corresponding to the one used in the NF EN 14683+AC. After dilution, the fractional number concentration was measured upstream and downstream of the mask with respectively an optical counter (Welas Palas®) and an Aerodynamic Particle Sizer (Model 3321 TSI®).

The fractional efficiency, efficiency for a given particle size, is calculated as follows:

$$E_N(d_p) = 1 - \frac{C_{N,\,down}(d_P)}{C_{N,\,up}(d_P)}$$

where $C_{N,up}$ and $C_{N,down}$ are respectively the particle number concentration upstream and downstream of the filter for a given DEHS droplet size (d_p).

The efficiency measurement was achieved from a series of 7 counts conducted successively upstream and downstream of the filter. Before each measurement, a sampling of 30 s is performed in order to purge and stabilize the concentration of particles in the sampling lines. These 7 counts give three efficiency results for the same mask sample (repeatability test). Efficiency measurements are conducted on three or four samples cut in one or two medical face masks (reproducibility test).

2.8. Workflow Stage 6: breathability

In accordance with the Standard NF EN 14683, the pressure drop of

the mask was determined at a filtration velocity of 27.2 cm/s. This differential pressure should be divided by the standard filtration area of 4.9 cm^2 before being compared with the normative values of <40 Pa/cm^2 for type I and II, and <60 Pa/cm^2 for type IIR.

2.9. Workflow Stage 7: projection resistance

For these measurement the masks, the experimental set-ups proposed by ISO 22609:2004 standard were adapted to the materials and equipment available in the labs. The experimental devices were validated by monitoring the corresponding injection pressure and injection duration with reference to those given by the ISO norm table. The projection resistance tests were performed under the conditions described by the ISO Standard, at a blood ejection rate of 550 cm/s corresponding to a blood pressure of 16 kPa. The tests were repeated once for each type of mask under the same conditions. To be fully compliant with ISO 22609, nearly 30 tests should be performed for each type of mask, which is obviously not possible in the current context (SI-5a and -5b).

2.10. Workflow Stage 8: chemical and structural characterizations

Fourier Transform Infrared (FTIR) spectroscopy and Scanning Electron Microscopy (SEM) experiments were conducted to complete the workflow. Each protocol is described in SI-8a and -8b.

3. Results

3.1. Cleanliness after workflow: macroscopic inspection of the washed masks

For this stage of the Workflow an initial mask sorting step was performed before the washing step. Some masks were excluded from the washing because they were too dirty, mostly due to make-up smears (around 3–4% of the total collection). Masks with low quantity of makeup were well cleaned. We've noticed during this study, that around 1% of the collected masks were repaired with a staple, which highlighted the shortage of masks during the collection periods. Up to 10 washing/drying cycles did not modify the appearance of the mask.

The visual inspection of the new CA diffusion 1960 masks after washing did not show any significant structural defect, apart from broken elastic ear-loops (5–7% of the masks) that always at the welding spot between the mask and the elastic band. Minor rust spots are appearing on 25% of the mask at the two ends of the nasal bar after 2 washing cycles. Those rust spots do not have any adverse effect on the face mask fitting.

Similar results were found with the 9 used collected different brands in Grenoble and 10 different brands in Nancy. All the masks look clean, without any dimensional change, 5% of the mask had a broken elastic ear-loop, rust spots were observed on 1/3 of the masks (Fig. 2a). We have noted that for 50% of the Euronda masks the nasal bar was able to dislodge from the sheath on the mask.

3.2. Cleanliness after workflow: microbial inspection of used masks

We applied to our washed masks the same tests applied for new fabricated masks in accordance with NF EN 14683. For this, we extracted randomly 5 masks from 4 different washing batches and measured the number of bacterial and fungal CFU present on each mask. The results (SI-3b) met expectations as the total measured CFU is 5 times less than the limit described in the norm ($\leq$ 30 CFU/g). Nonetheless, the variability from one mask to another is large (Fig. 2c) with 1/3 of the mask containing between 6 and 9 CFU/g and 1 mask containing 29 CFU, which corresponds to the maximum allowed by the norm.

3.3. Cleanliness after workflow: masks washed in dirty conditions

Washing tests performed with 40 new masks in the dirty conditions recommended by the norms (SI-4a). Each new mask was soiled with 100 μL inoculum of the "dirty suspension" and then dried before the treatment (Fig. 2b). The blood stain was completely cleaned by the washing step. It may be noted that the permanent marker used to mark the spot is still present. Thus, the permanent marking of a used mask ensures easily a good traceability during all processes, and particularly during the tread life of a recycled mask.

We have also conducted an experiment to consider the worst possible case of spotting 10^6 spores of *G. stearothermophilus* in dirty conditions onto 5 new masks. A 4 log_{10}-fold reduction of spores was observed after washing. Spores are considered as the most resistant living organisms and are a good standard for a quality control. The SAL of 10^{-6} was largely achieved with a following sterilization step, for example by autoclaving the masks 20min at 121 °C (Fig. 2d and SI-4b).

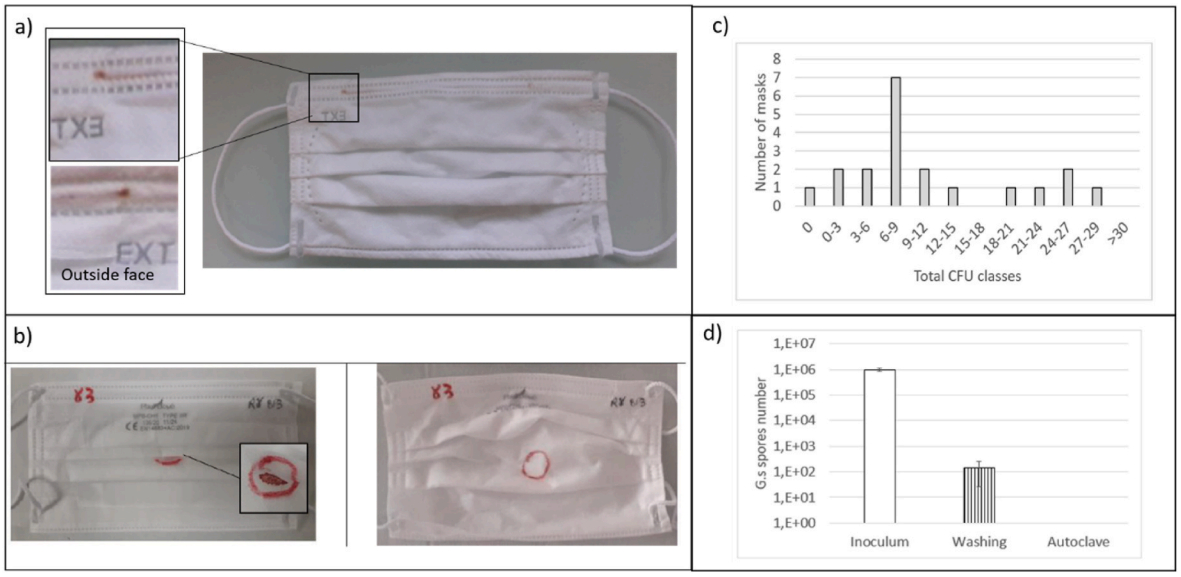

Fig. 2. a) Rust spots at the extremity of the nasal bar of a mask b) Mask (before/after) washed in dirty conditions c) Microbial distribution after a washing step d) Geobacillus stearothermophilus count after treatment in dirty conditions.

3.4. FE after workflow

The results of BFE (mean and spectral) and spectral PFE are presented in Table 1 and SI-6a,b,c for the treatments of new masks "CA diffusion 1960". Several batches comprising at least 5 masks were first treated, in particular washing cycles, washing cycles followed by autoclaving cycles and washing/alternative sterilizing cycles. The first line of the table (L201, L203, L204, and L327) corresponds to the untreated masks. Regardless of the treatment used, the filtration properties were preserved as quantified by the mean BFE greater than 99.6% ± 0.3 according to the NF EN 14683 standard (SI-0). These results indicate that those treated face masks passed the standard thresholds for filtration efficiencies, despite the possibility that the 3 layers of the masks could have separated during washing.

The spectral filtration efficiencies obtained by CFU counting for the BFE and by optical counting for PFE (Table 1) comply with the approved standards for particle size greater than 1 μm. For 3 μm particles, spectral BFE and PFE are always higher than 99.0% ($\%_{CFU}$ or $\%_{OPTICAL}$) indicating that the different treatment processes (until 3 or 10 cycles according to the treatment) do not seem to deteriorate the protective performance of those face masks. Alternative cold sterilization procedures, i.e radiations and EO treatment, are described in SI-2 section and in a preliminary IAEA report (Cortella et al., 2020). No degradation of PP and EO residues were found after treatment. Some minor chemical modifications, were measured mostly due to the presence of anti-oxidants in new masks.

The differences between the two sets of spectral PFE measurement can be explained by the use of two different experimental devices inducing differences in (i) the filtration section which a ratio of 6 (168 and 28.3 cm^2), (ii) distribution, and concentration of the liquid particle size of the DEHS generated by the two systems, (iii) the particle counting systems, which are based on two different principles of particle size measurements (optical counter based on light diffraction and aerodynamic sizer based on time of flight).

For submicron-sized particles (impaction plate collecting size fraction between 1.1 and 0.65 μm for BFE, and particle size of 1, 0.67 and 0.3 μm for PFE), the BFE and PFE values are different but show the same tendency for FE to decrease with particle size and the influence of the treatment processes, which altered the efficiency for those fine particles but without degrading the mean BFE values. We have noticed that this loss of efficiency for submicron-sized particles is effective after the first wash and stabilized at the same level after several washes, regardless of the washing process (SI-6b). At submicron-size, the filtration involves other mechanisms than inertial impact that can particularly include electrostatic mechanisms. This electret effect (Lin et al., 2017; Hossain et al., 2020) of the polypropylene fibres is permanently destroyed during the first wash because the washing agents bind to the surface and cannot be removed. This effect can be mimicked by the rinsing of a new mask in isopropanol (SI-6c). Results show that the discharging of a mask leads to the same spectral collection efficiencies than those of a washed mask, confirming the loss of electret effect as a result of the first washing cycles.

Used medical masks come from hospital departments and consist of 9 different reference brands (Table 2). They have undergone 5 washing cycles followed by 5 autoclave cycles. After sterilization and washing, the filtration properties were conserved for all the samples, with a minimum mean BFE of 98.2% ± 1.2 for the sample with the lowest filtration performance, which is above the NF EN 14683 standard threshold. The comparison of spectral BFE and spectral PFE (Table 2 and SI-6d) confirms the good protection performances of the used masks after 5 decontamination procedures for particle sizes higher than 2 μm ($BFE>99.6\%_{CFU}$ and $PFE>97.2\%_{OPTICAL}$). Even if some differences can be observed between these 9 reference brands, results show a preservation of the spectral BFE and PFE for particle size higher than 2 μm whatever the mask. A significant decrease of spectral efficiencies (both BFE and PFE) is observed for particle size smaller than 2 μm, even

Table 1
Filtration efficiency after new masks treatments. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. * FPE results from LRGP Nancy for intercomparison with IMT Nantes. Und-: Undetermined

		Washing	Sterilization				Filtration analyses after treatments								
Batch number	Mask number	Washing 60 °C 12 min Ultimate (F + M)	Autoclave 121 °C 20 min	γ rays 20 kGy	Electron beam 40 kGy	Ethylene Oxide	Bacterial filtration efficiency norm NF EN 14683 AC	Fractional bacterial filtration efficiency norm NF EN 14683 AC				Fractionnal particle filtration efficiency				
								3.3–4.7 μm	2.1–3.3 μm	1.1–2.1 μm	0.65–1.1 μm	3 μm	2 μm	1.6 μm	1 μm	0.67 μm	0.3 μm
L201, L203, L204, L327	20	–	–	–	–	–	**99.98 ± 0.03%**	100.00%	100.00%	99.93%	100.00%	99.99% 99.95%*	99.96%	99.90%	98.26%	80.06%	40.17%
L202, L205, L206	15	1	–	–	–	–	**99.9±0.08%**	100.00%	99.96%	99.52%	90.77%	99.99% 98.44%*	99.88%	99.71%	98.48%	88.85%	35.25%
L209	10	3 cycles	–	–	–	3 cycles	**99.89 ± 0.05%**	100.00%	100.00%	99.19%	91.58%	100%	99.9%	99.8%	91.8%	64.75%	40.0%
L212	10	3 cycles	–		3 cycles	–	**99.61 ± 0.37%**	99.81%	99.50%	99.84%	60.00%	99.2%*	98.0%*	94.0%*	–	–	–
L215	10	3 cycles	–	3 cycles	–	–		–	–	–	–	100%	99.85%	99.7%	93.7%	60.33%	30.37%
L216	10	1	1	–	–	–	**99.8±0.11%**	100.00%	100.00%	98.99%	Und–	100%	99.88%	99.0%	96.9%		
L252	10	–	10 cycles	–	–	–	**99.73 ± 0.33%**	99.95%	99.94%	98.69%	77.60%	–	–	–	–	–	–
L221	10	10 cycles	–	–	–	–	**99.79 ± 0.09%**	100.00%	100.00%	99.16%	93.78%	98.97%*	–	–	–	–	–
L316	10	–	–	–	–	3 cycles	**99.93 ± 0.10%**	100.00%	100.00%	99.88%	76.00%	99.99%	99.99%	99.8%	–	–	–

Table 2
Filtration efficiency of used mask after 5 washing steps followed by 5 autoclaving steps. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. * FPE results from LRGP Nancy for intercomparison with IMT Nantes.

Batch number	Mask number	Mask brand	Bacterial filtration efficiency norm NF EN 14683 AC	fractional bacterial filtration efficiency norm NF EN 14683 AC				Fractionnal particle filtration efficiency					
				3.3–4.7 μm	2.1–3.3 μm	1.1–2.1 μm	0.65–1.1 μm	3 μm	2 μm	1.6 μm	1 μm	0.67 μm	0.3 μm
L271, L107	20	Used Paul Boyé MPB-CH1	**99.89 ± 0.11% 99.82 ± 0.12%**	100.00%	100.00%	99.57%	73.33%	99.88%	98.91%	98.6%	94.89%	68.72%	39.54%
L272	10	Used CA diffusion unknown ref	**98.18 ± 1.06%**	100.00%	99.65%	84.74%	20.00%	91.90% *	63.20% *	44.6%*	–	-	-
L103	10	Unknown 1 (Blue 1)	**98.91 ± 1.22%**	99.92%	100.00%	93.92%	46.67%	99.99%	98.9%	97.5%	82.41%	45.92%	28.3%
L104	10	Used Kolmi Op'R M36101	**99.19 ± 0.26%**	99.93%	99.87%	95.30%	18.00%	99.39%	97.22%	93.45%	71.47%	37.69%	25.85%
L105	10	Used CA diffusion	**99.09 ± 0.27%**	100.00%	99.91%	95.54%	3.16%	99.99%	97.78%	94.98%	74.10%	40.11%	24.63%
L106	10	Used Valmy	**99.82 ± 0.07%**	100.00%	100.00%	98.63%	88.00%	88.38%	87.48%	86.32%	72.99%	37.51%	24.01%
L108	10	Used unknown 2 (Blue 2)	**99.62 ± 0.20%**	100.00%	99.97%	98.22%	20.00%	98.30%	98.62%	97.24%	80.29%	42.38%	25.74%
L109	10	Used unknown 3 (white light)	**99.75 ± 0.08%**	100.00%	100.00%	98.19%	42.86%	98.25%	93.40%	92.09%	75.16%	36.00%	17.81%
L110	10	Used Euronda	**99.80 ± 0.12%**	100.00%	100.00%	98.75%	73.33%	99.99%	99.91%	99.66%	94.23%	61.40%	33.14%
L111	10	Used CA diffusion 1960	**99.80 ± 0.09%.**	100.00%	99.96%	99.20%	91.25%	99.99%	99.96%	99.94%	96.14%	66.22%	36.53%

though the BFE shows a good filtration performance of greater than 91.2% for submicron particle sizes in the range 0.65 μm–1.1 μm.

To check the influence of a hole or a notch that can occur accidently in the mask during the recycling process, we deliberately damaged a series of mask after one use/washing/autoclave cycle and tested their FE. Holes were created in the center of the masks in two ways. The first was to pierce the mask material with a blunt cylindrical tool such as a Phillips screwdriver to create holes from 1 to 5 mm. The second was to use a razor blade to make cuts of 7 and 10 mm. Those techniques punctured the mask material and created a rough-sided hole from 1 to 5 mm or a clean side cut of 7 and 10 mm without explicit removal of the material within the confines of the punctured hole. Indeed, an accidental explicit removal of material with a hole puncher is highly unlikely compared to a tear (as we have simulated with the razor blade cuts). The figure SI-6e shows results of PFE measurements performed on a medical mask (L101) and on the same mask with holes of different sizes on the center part of the mask face (L102 with hole of respectively 1, 2, 3, 4, 5 mm and cuts of 7 and 10 mm size). Due to the multi layer media constituting the mask, even in the case of big holes (>3 mm) no significant influence is observed for spectral efficiency for particle diameter higher than 1 μm (apart for the test performed with a hole of 2 mm for which a slight decrease of PFE is observed). For particle sizes lower than 1 μm, the presence of holes in the mask can contribute to a slight decrease of the spectral efficiency compared with the mask without any hole.

3.5. Breathability after workflow

The breathability performances (resistance to air flow) were not significantly affected regardless of the particular decontamination process. When compared with untreated masks, breathability values remained within the variability range of measurements made on the untreated masks (variation due to the intrinsic local heterogeneity of the fibrous structure composing the masks) and were always under normative values, i.e. of 40 Pa/cm^2 for a type I or II and 60 Pa/cm^2 for a type IIR. The Mann-Whitney *U* test (Spiegel and Stephens, 2008), a non-parametric statistical test applied to data, confirmed that the breathability of treated masks (regardless of the type of treatment) is not significantly different from that of the untreated masks. Thus, we can conclude that the sterilization and washing cycles do not alter the structure of the non-woven media.

3.6. Projection resistance after workflow

The projection resistance ("R" function) was tested on an experimental set-up aiming to reproduce the test conditions recommended by ISO 22609:2004 Standard. This set-up was developed, validated and implemented on new or washed masks with a synthetic blood formulation. The "R" function was lost after a few washing steps, regardless of the particular brand of type IIR mask. It appears that washing changes the surface properties of the outer layer of a washed mask which leads to the loss of the protective function (SI-5c). The projection resistance is not maintained after recycling, which means that medical team working in an operating room should not wear washed IIR masks.

3.7. Chemical and structural characterizations

The two broad ranges from 2835 to 2952 cm^{-1} and from 1165 to 1452 cm^{-1} of FTIR spectrum are characteristics of polypropylene. The FTIR analysis does not reveal significant oxidation processes after cleaning (SI-8a).

SEM images of treated masks are presented in SI-8b. No significant morphological modifications were noticed, except for MPB-CH1 melt-blown layer containing thinner fibres (SI-8b). However, these modifications do not impact the filtration that remains very high (Table 2).

4. Discussion

4.1. Cleanliness, filtration and breathability of type II medical masks remain compatible with EN14683 after up to ten cycles of washing cycles at 60 °C with detergent

Reuse must ensure the conservation of the paramount properties of the mask. We have proven that the process of washing/sterilizing the masks retains their cleanliness, their filtration capabilities and their breathability. However, the R function is lost in the cleaning process. This does not detract from the function of the masks in a domestic usage, but requires a modified usage of reused masks in the hospital environment. Although reused masks can no longer be used appropriately where blood or bodily fluid splashing can occur, such as in operating rooms, the reused masks can be used appropriately in other areas of the hospital. It is important to note that in any case type IIR masks are already dedicated to operating rooms.

The cleanliness of the masks is obtained by washing. This washing step is mandatory to respect good hygiene practice before any other treatment and acceptability for the user. The aim of the washing step is to eliminate all traces of biological contamination (secretions, mucus) and to lower the level of initial contamination (due to the 12min contact with disinfectant). Moreover, it tackles a large part of the problem of wearing a mask that is not your own. Indeed, even if a mask is sterilized, it is difficult to wear a used dirty mask that has not been washed. The SARS-CoV-2 is a virus sensitive to the combined action of detergents, mechanical movements and heat which occur in a washing machine. The commonly accepted recommendation for cloth-tissue mask is a washing step at 60 °C, or even lower (FNAM, 2020). As recommended for community use of masks, a sterilization step described in SI-2c is not recommended.

The results of excellent FE remaining after even 10 cycles of washing has very positive sanitary consequences on the wearing of used/washed masks in the domestic environment, especially in the context of severe constraints on mask shortage or indeed the reduction of discarded single-usage masks on the environment.

4.2. Collective treatment of the masks needs a sterilization step

Mask reuse in a collective reprocessing generates more complexity, taking into account good hygiene practice and healthcare waste management. Although Kane et al., 2018, describe that “introducing circular economy principles into design for healthcare is challenging”, it is nonetheless an important point to address. It is critically important to consider the bacterial and fungal cleanliness of the recycled masks used in a healthcare environment. It is indeed required to eliminate all potential risks of bacterial or fungal cross-contamination of masks potentially exposed to microbiological agents of the wearer or of its environment.

The 4 $\log_{10}$ spores reduction obtained with washing is in accordance with an experiment performed in Bangkok’s hospital (Luksamijarulkul et al., 2014), which evaluates the bacterial and fungal contamination on used medical masks worn by the HCW. The authors collected 230 used masks from 214 HCW and found that the maximal bioburden was less than 10^3 CFU/mL/piece on the outside area of the masks and less than 10^2 CFU/mL/piece in the inside area of the masks ($p < 0.001$). In principle, this first washing step should be sufficient to eliminate the microorganisms that are present on the masks. Nonetheless, in the special case of a pandemic, especially for a virus pandemic, it is important to reduce the contamination risk to ensure a health and safety state (Bernard et al., 2020). Moreover, the analysis of the variability of the cleanliness of washed masks suggest that a safety state is not achieved by a washing step procedure using masks coming from the hospital. The issue can also come from organisms that can be found in a hospital: Hepatitis B Virus or *Mycobacterium tuberculosis* are also thermoresistant up to 80–100 °C (Doig et al., 2002, König et al., 2019). Thus, other methods have to be applied after the washing process to ensure a perfect recycling quality.

The reuse of cleaned mask is somehow not sufficient to provide enough safety for HCW and a sterilization step is mandatory, not to have a sterile status of the device but to minimize this risk of cross-contamination of resistant germs like spores or mycobacteria. The existing circuits of sterilization process of autoclavable tools and dirty laundry transfer circuit (Fig. 3) greatly facilitated the operating procedure in a healthcare environment.

The industrial sector can also consider a collective recycling. Some companies have already shown a willingness to make progress in the ecological consequences of polypropylene recycling by creating specific recycling branches dedicated to medical masks. Despite those good intentions, those small number of companies do not have sufficient financial resources to expand those recycling activities. Nonetheless, those examples add value to the global waste management, because before the masks are either discarded or recycled they are first reused. The risk of cross contamination in the industrial sector is often less present than in hospitals and the washing step is probably enough to guarantee the safety. This risk can be evaluated on a case-by-case base. However, the possibility of sterilizing is still possible with access to different technology platforms described in Table 3.

The presence of autoclaves in sterilizing unit facilitates this process but the major drawback is the number of units that can be treated at the same time. The β and γ technologies have some differences in the process. Gamma ray technologies make it possible to deliver the dose to a large volume of masks but slowly, while electron beam technologies, on the other hand, make it possible to achieve the same dose in a fraction of a second, but in a smaller volume. The net result is that β and γ technologies are comparable in processing capacity. Density is also a relevant factor that influences on the penetration of radiation, and thus on the processing capacity. At this stage of the study, there will be no noticeable difference between β and γ radiation because the number of masks was small. They were wrapped into vacuum bag to reduce the thickness of each bag (more than one half-volume reduction), allowing the handling and the cleanliness of the masks until their reuse. A performance qualification study will have to be carried out in each case when the process will be industrialised.

EO treatment and irradiation treatments β and γ are cold sterilization alternative techniques to autoclave treatment. Despite the fact that the logistics have to be created unlike the washing/autoclave circuit, they are useful tools to process a huge quantity of masks at the same time in a single run. Supercritical carbon dioxyde-based treatments have very recently been successfully designed to allow cleaning and sterilization of medical masks or even Filtering Face-Piece respirators (N95/FFP2) (Cario et al., 2021).

4.3. Biocompatibility preliminary data

The results of FTIR and SEM analyses performed on the treated masks are very reassuring: they tend to indicate that the treatment yields no major modification of the physico-chemical components of the masks. Besides, most of the reusable cloth-tissue masks contain as much polypropylene as medical masks, and are certified for reuse after between 10 and 50 washing cycles. No adverse event related to wearing washed cloth-tissue masks was reported, although millions of such masks were washed and reused all over the world. Therefore, demonstrating biocompatibility will be necessary only for manufacturers wishing to demonstrate full consistence to EN 14683 of washed masks.

4.4. The conformity with the French standardization association (AFNOR) SPEC S76-001: 2020 allows not only to issue recommendations for the public, but also to perform a clinical trial in real conditions

The washing conditions for reusable cloth-tissue masks are described in similar rules for each country (FNAMHPS, 2020 for France). Our

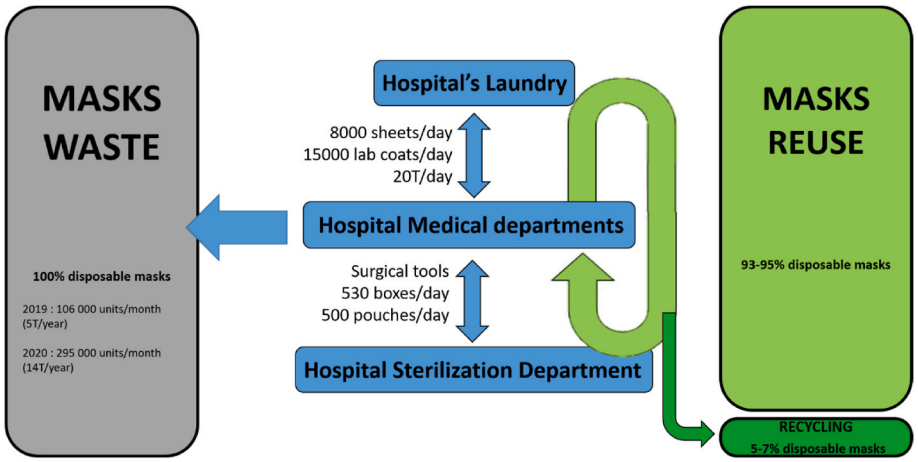

Fig. 3. Waste management. Existing circuit (blue and grey, on left). Masks Reuse and Recycling circuit (green, on right). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 3
Comparison of different treatments capacity and duration for medical mask reuse in collective settings.

Methods	Washing	Autoclave	β Radiations	γ Radiations	Ethylene oxide
Location	Hospital	Hospital	IONISOS	CEA/IONISOS	IONISOS
Number of treated masks/cycle	5000	1200	170 000	>1 million	up to 1 million
Conditions	Detergent +disinfectant +60 °C/12 min	121 °C/20 min.	25 kGy vacuum	25 kGy vacuum	850 mg/L-40°C-65% RH/12 h
Treatment duration	2 h	7 h	<1 h	12 h	60 h
Estimated global recycling time (including transport)	1 day		3 days	3 days	6 days

washing conditions were more demanding (60 °C instead of 40 °C). The conformity according to the French AFNOR SPEC S76-001: 2020 for cloth-tissue masks of 3 brands of medical masks washed up to 10 times under these conditions has been checked with success by independent certified actors (SI-7). This conformity, in accordance with European CWA 17553:2020 and US F2299/F2299M – 03 regulations, allows to recommend the reuse of washed medical masks instead of cloth-tissue masks to guarantee a higher level of filtration. Indeed, the quantity of 3 μm particles emitted towards the entourage of a person in 6 min without any face protection is equivalent to the quantity emitted in 1 h with a 90% filtering cloth-tissue mask or in 5 h with a medical face mask filtering at 98% (SI-0).

The loss of the CE marking led to the loss of legal status for the treated masks (which are non-reusable Medical Devices). A legal status is recovered by the AFNOR certification that will allow to test wearing/treatment cycles in a future clinical trial. The main objective of this clinical trial will be to demonstrate that at least 10 cycles of use/washing and at least 5 cycles of use/washing/sterilization can be done in real conditions with full compatibility with EN14683 norm (including complete test of biocompatibility, which as previously discussed was not completely tested in the present work).

4.5. Mask end of life

The major issue is the limit of cycles that can be done. We arbitrarily stopped after 10 cycles of washing, which preserves the filtration properties of the masks. The number of cycle treatments will depend on wearing, washing and storing conditions. How to know when the mask is no more useable? The answer is probably "when it does not fit well to the face". This answer is due to several reasons. First of all, the structure of the mask: each layer is a non-woven material. When a cut in the fibres occurs, the thread is not uncoiled. Holes or notches in a cloth-tissue mask, which are woven or knitted, will have a devastating effect on the filtration. Secondly, the 3 layers of material can slide one on the other and this phenomenon plugs cracks or holes so that the filtration capability is maintained, as shown in Fig. 3b. Finally, the most fragile parts of the mask are actually the nasal bar, the ear loop elastic band and especially their welding spot on the corners of the mask. The accumulation of lint can be observed after several washes at home with short cut fibres going out of the mask outside layers. This pilling leads to uncomfortable wear and can define the end of life of the mask even if filtration properties remain efficient.

4.6. Economic perspective

The reuse of medical mask opens new perspectives. The mask reuse has also a significant economical effect on households: The price of a tissue mask, with a guarantee of 50 washes, can reach up to 50 times the price of a medical mask. Thus, a medical mask washed 10 times is 10 times cheaper. The cost of washing is zero has the masks are washed with the washing of domestic clothes.

In collective treatment, the recycling price has to be evaluated according to the number of masks used per day, the presence of a recycling process or the strategic partnership with appropriate companies.

4.7. Ecologic perspectives

Covid-19 pandemic has led to a widespread of environmental contamination of plastics, comprising the polypropylene medical masks. At a large scale or in highly specific environment, the low cost of disposable masks compared to the cost of recycling its polypropylene is probably not a viable economical target, because of the low weight/volume of each mask, its infectious risk and the lack of existing recycling circuit. However, the ecological cost will more expensive at the end-of-mask-life. The rational reuse of medical mask and their end-of-live management is critical, particularly in pandemic periods when decisive turns can be taken. The reuse is the first step of a recycling process.

The use of disposable masks in the general population gives rise to

their larger consumption to help fight high transmissible mutants but their reuse up to 10 times will compensate or will even reduce their environmental impact. For lower scale uses, the possibility to safely recycle medical masks is cost-effective, and an eco-friendly gesture.

Ecological consequences must be taken into account: a non-woven mask is easily recycled as it is only composed of pure polypropylene when the nasal bar and the elastic bands are removed. This is not the case for woven masks that often uses a mix of synthetic fibres and has to follow a specific recycling. However, the recycling of domestic usage of medical masks has not been yet envisaged.

5. Conclusion

We have proven that the lifetime of type II medical face masks can be extended by reusing them after washing and decontaminating treatments. Those treatments consist in washing steps and/or washing sterilizing cycles. The use of a detergent and a disinfectant during the washing step allows not only to clean the device but also to reduce the presence of germs. The masks retain their breathability and their filtration capability up to 10 cycles of washing or 5 washing cycles followed by 5 autoclaving cycles without major structural and chemical modifications. Cold sterilizations, like radiations or EO treatment have also been tested with success. These experiments prove that those "disposable" masks remain reusable, with the exception of the anti-projection resistance that is not conserved, so that the masks cannot be reused in operating rooms. As washed medical masks remain more efficient in terms of filtration than cloth-tissue masks, we can recommend their reuse according to the cloth-tissue mask regulations. A clinical trial in real conditions with full compliance with EN 14683 norm will allow the manufacturers to claim that type II medical face masks can be considered as Medical Devices after washing (followed or not by a sterilization process). This will require modifications of laws and regulations in countries like France, where legal prohibitions prevent any reuse of a "single-use" Medical Device. However, we have demonstrated here that type II medical face masks are compliant with the regulations applicable for reusable cloth-tissue masks. This may have a tremendous impact in terms of public health and ecology. In terms of public health, wearing a type II medical face mask provides a much better protection than a cloth-tissue mask. In terms of ecology, reusing 10 times a type II medical face mask would reduce the burden associated with the waste management and the consumption of polypropylene.

Author statement

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors, except one, declare that they have no known competing financial interest or personal relationships that could have appeared to influence the work reported in this paper. Sophie Rouif is Research & Development Leader in the company IONISOS SAS, dedicated to industrial sterilization and provided results for irradiations and ethylene oxide treatments.

Acknowledgments

We thank: Nicolas Alberto, Françoise Bionier, Sophie Brionne, Yves Grenouiller, Sylvie Guillot, Séverine Marcel, Marta Pastor-Nietro, Angelina Pollet, Sabine Revel, Françoise Roux, Saber Touati from all health care departments of the CHUGA. We also thank Béatrice Genoux, Marion Proust, Sandrine Massicot, Emilie Bruckert, Véronique Dubois, Jérémy Herman, Laure Caillard, Stéphane Lemasson for availability and mask collection and washing. We thank Patrick Meresse and his CUBE for petri dishes donation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.chemosphere.2021.132364.

Funding information

This study has been carried out in the framework of a French scientific consortium initiated by Centre national de la recherche scientifique (CNRS) and Commissariat à l'énergie atomique et aux énergies alternatives (CEA) with a close collaboration with Grenoble and Nancy University Hospitals where the masks were collected. It was funded by the Centre National de la Recherche Scientifique (CNRS) and by the own

resources of each lab during the first confinement period in France (march–june 2020).

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